Dispatcher-Assisted Cardiopulmonary Resuscitation: A Randomized Controlled Trial of Low-Dose, High-Frequency Simulation-Based Training and the Impact on Real Out-of-Hospital Cardiac Arrest Calls

General Information

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Funding: The study is financed by an unrestricted research grant from the Danish foundation TrygFonden.

Trial registration

The protocol will be registered on ClinicalTrials.gov prior to enrolment and randomisation of participants. All items from the World Health Organization Trial Registration Data Set will be reported.

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Participants will be enrolled and randomized in the start of September 2019.

Data collection is planned to start in mid-September 2019 and run for 13 weeks.

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Abbreviations:

AHA American Heart Association

AED automated external defibrillator

BLS basic life support

CBD criteria-based dispatch

CPR cardiopulmonary resuscitation

DA-CPR dispatcher-assisted cardiopulmonary resuscitation

EMD emergency medical dispatcher

EMDC emergency medical dispatch centre

EMS emergency medical service

ERC European Resuscitation Council

LDHF low-dose, high-frequency

LLEAP Laerdal Learning Application

OHCA out-of-hospital cardiac arrest

RQI-T Resuscitation Quality Improvement for Telecommunicators

BACKGROUND

The chance of surviving an out-of-hospital cardiac arrest (OHCA) is reduced by 7-10% each minute defibrillation is delayed[1]. If early cardiopulmonary resuscitation (CPR) is provided in the time period until defibrillation, the chance of survival is only reduced by 3-4% per minute[1, 2]. Dispatcher-assisted CPR (DA-CPR) can strengthen the chain of survival by increasing the bystander CPR rate and quality as well as diminishing the time to CPR[3-8]. Additionally, the emergency medical dispatcher (EMD) can act as a team leader and assist the bystanders in providing high-quality CPR. Several studies from multiple countries and continents have found increased survival with DA-CPR[3, 4, 7, 9-11]. The European Resuscitation Council (ERC) and American Heart Association (AHA) have in recent years and with the latest guidelines, emphasised the importance of the EMDs in OHCAs, and the Global Resuscitation Alliance (GRA) recommends DA-CPR as one of the "10 Steps for Improving Survival From Sudden Cardiac Arrest" [12-16].

Around the world, dispatcher protocols have been developed to ensure the quality of the EMDs' support, and studies show that the implementation of such protocols increase bystander CPR and survival[6, 17, 18]. In Denmark, Danish Index for Emergency Care (Dansk Indeks for Akuthjælp) is a triage and decision tool for EMDs to guide the caller and decide the appropriate emergency medical service (EMS) response[19, 20]. The Danish version is a translation and adaptation of the Norwegian Index for Emergency Medical Assistance Norwegian (Norsk Indeks for Medisinsk Nødhjelp), version 3, which was based on the principles of the criteria-based dispatch (CBD) system developed in King County, Seattle, USA[21]. One of the fundamental principles of many CBD systems is a set of all-caller questions at the beginning of every call, to rule out or recognise a cardiac arrest. This concept has been described as "No-No-Go". The EMD is to determine whether the patient is conscious and if not, determine whether the patient breathing normally[22]. If the caller responds "no" to both consciousness and normal breathing, the EMD must send an EMS response as well as provide DA-CPR instructions without further delay or elaborating questions. Thus, with two simple questions in mind, the EMD can recognise or rule out a potential cardiac arrest, activate the appropriate EMS response and initiate bystander.

Various methods are used in training EMDs to recognise cardiac arrests and provide quality DA-CPR instructions: dispatcher-to-dispatcher audits of emergency call records, simulation-based training, case reviews, mentor groups, reporting, and feedback[23, 24]. Introduction of structured CPR instruction protocols have also been shown to have a positive effect on bystander CPR, and

thus survival, but protocol adherence is not perfect[25-27]. While their role in the Chain of Survival is paramount, each EMDs often handle relatively few OHCA calls every year, thus regular training is essential to maintain competences[28, 29]. The Global Resuscitation Alliance has, through the Resuscitation Academy (Seattle, Washington, USA), together with The American Heart Association (AHA) and Laerdal Medical (Stavanger, Norway), developed a simulation training program for EMDs that meets these needs: structured training that requires only few resources. Despite the vast literature on medical simulation training, there is a knowledge gap regarding the potential benefits of low-dose, high-frequency (LDHF) training of EMDs using structured feedback. The potential benefits have not yet been investigated in real OHCA. This study will obtain evidence to the use of LDHF simulation-based training for EMDs.

STUDY AIMS AND HYPOTHESES

The aims of this study are:

- 1) To measure the effect of LDHF simulation-based training on the quality of DA-CPR in a simulation setting.
- 2) To measure the effect of LDHF simulation-based training on the quality of DA-CPR in real OHCA calls.

We hypothesise that LDHF simulation-based training will increase the quality of DA-CPR in the intervention group in a simulation setting and that this improvement is transferred to real OHCA calls – although the effect in real OHCA calls might be smaller due to the complexity of some calls. We hypothesise that this improvement can be detected as a decrease in time to first bystander compression (TTFC), an increase in clarification of consciousness and breathing without asking additional questions, a decrease in time to recognition of cardiac arrest, and an increase in calls where the EMD provide DA-CPR instructions on patients in cardiac arrest.

STUDY METHODS

STUDY DESIGN

The study is randomised controlled trial comparing LDHF simulation-based training to standard quality improvement of the EMDs in a single centre. This protocol is structured according to the SPIRIT 2013 statement and the study will be reported in compliance with the CONSORT 2010 Statement[30, 31]. We choose EMDs receiving standard quality improvement as the comparator group, to reflect a representative cohort of the EMDs not exposed to the LDHF simulation-based training program.

OUTCOME MEASURES

Primary outcome:

1. Time from a call is taken by EMD to first bystander compression (seconds)

Secondary outcomes:

- 2. EMD clarifies status of consciousness and breathing before asking any additional questions (yes/no)
- 3. Time from a call is taken to the recognition of cardiac arrest (seconds)
- 4. EMD starts DA-CPR instructions (yes/no)
- 5. Time from a call is taken to EMD starts DA-CPR instructions (seconds)
- 6. EMD is assertive when starting CPR instructions (yes/no)
- 7. EMD starts DA-CPR instructions on patient without cardiac arrest (yes/no)

All outcomes will be assessed in both simulated calls and real OHCA calls.

STUDY SETTINGS

The study will be conducted at Copenhagen EMS, the emergency medical dispatch centre (EMDC) covering the Capital Region of Denmark. The Capital Region of Denmark covers Greater Copenhagen including suburbs and has a population of approximately 1.84 million people covering an area of 2559 km³[32]. The European emergency phone number 1-1-2 life-threatening calls and injuries is the countrywide, which connects the caller to a switchboard identifying location and need for police, fire department, or medical assistance. Medical emergency calls in the Capital Region of Denmark are transferred to the Copenhagen EMS, which receives approximately 105,000 emergency calls annually, of which approximately 1,200 (~1.0%) are OHCAs. The call taker is a paramedic or a registered nurse.

PARTICIPANTS

All approximately 70 employed EMDs at the Copenhagen EMS, guiding callers in emergency situations, will be assessed for eligibility, except for the four EMDs facilitating the simulations (see below).

The following eligibility criteria apply:

Inclusion criteria:

- EMD employed at the Copenhagen EMS at the time of enrolment

Exclusion criteria:

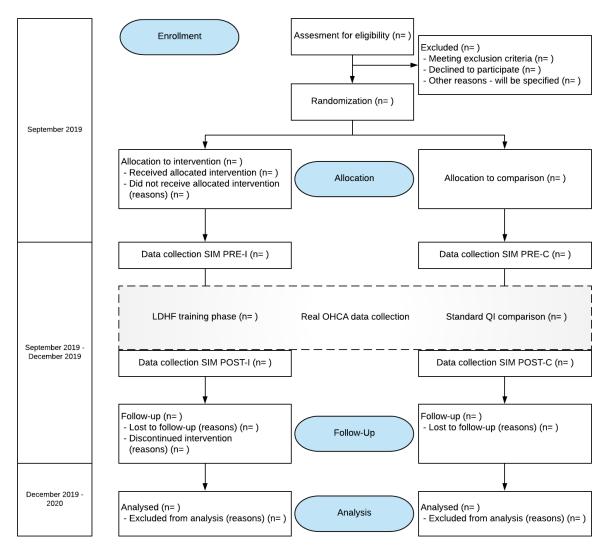
- Mean working time as call taker at Copenhagen EMS < 8 hours/week
- Planned employment cessation at the Copenhagen EMS during the data collection period
- Planned leave from work longer than four weeks during the data collection period
- Starting employment at the Copenhagen EMS during the study period

The flow of participants will be illustrated using a CONSORT 2010 Flow Diagram (Figure 1).

We expect to be able to obtain a follow-up on ~60 EMDs due to an anticipated loss to follow-up of ~8 %. Simulation-based dispatcher training for EMDs in the intervention arm will be held during the EMDs' regular paid shifts. Demographic data will be presented separately in each group. Numeric data will be presented as medians with interquartile ranges, and categorical data will be presented as numbers with percentage. The following demographic data regarding EMDs will be collected: age (years), sex (male/female), profession (paramedic/nurse), experience as an EMD (years).

Participation in the study is voluntary, without additional economic or other compensation. Both written and verbal informed consent of all EMDs will be obtained prior to randomisation. Further, EMDs can, at any point withdraw their consent and discontinue their participation without providing any reason.

Figure 1 – CONSORT 2010 Flow Diagram



LDHF: Low-dose, high-frequency; QI: Quality improvement; SIM PRE: Simulation preintervention; SIM POST: Simulation post-intervention; I: intervention group; C: comparison group; (n=) will be listed at the end of the study.

RANDOMISATION PROTOCOL

After enrolment and consent from the EMDs, the EMDs will be randomly assigned to receive either LDHF simulation-based dispatcher training (intervention arm) or no LDHF simulation-based dispatcher training (comparison arm).

The EMDs will be randomly assigned to intervention or comparison group in a 1:1 ratio. Randomisation will be stratified by the EMDs' medical backgrounds (paramedic, approximately 30% of the EMDs, or registered nurse, approximately 70% of the EMDs), to balance the number of EMDs with different medical backgrounds randomly assigned to each arm. All the EMDs will be

randomised at the same time using a randomisation programme written in R (R Core Team, R Foundation for Statistical Computing, Vienna, Austria). A random seed (ensuring that the same randomisation sequence can be re-generated) will be selected by a person not involved in the study, and the same person will run the script. This is done once after all eligible EMDs have either decided to participate or not. Thus, all eligible, consenting EMDs will be randomised at the same time and the randomisation scheme will be immediately delivered to the study group, without need for allocation concealment as the random sequence is generated at the same time as all participants are assigned to one of the two trial arms. The research group and the participants will not be blinded to the allocation, except for the study statistician (A.K.E.), who will conduct all analyses blinded to the intervention group. Thus, the study statistician will not have access to the randomisation scheme or the random seed and will receive a dataset with the actual groups replaced with the numbers 0 and 1.

SAMPLE SIZE

The required sample size (number of real OHCA calls) has been calculated based on the primary outcome; time from a call is taken to first compression, with 32 EMDs in each arm. This calculation is based on an expected inclusion of 70 EMDs and an anticipated loss to follow-up of ~8%, thus, follow-up of 64 EMDs is projected. Based on OHCA calls in November-December 2018, mean (standard deviation; SD) TTFC was calculated as 174 (111) seconds where TTFC initiated later than 10 minutes after call were excluded. With a comparison group mean of 174 (SD 111) seconds for TTFC and an expected TTFC in the intervention group at mean 120 seconds, we estimate a need of 160 real OHCA calls in each of the two arms to have 90% power to reject our null hypothesis of no change in TTFC with at a two-sided test and alpha level of 5%. An assumed intra-class correlation at 5% between TTFC within the same dispatcher is used in the calculation [33]. To reduce the risk of underpowering the study due to a smaller reduction or greater standard deviation, we aim to include data from 175 calls in each group but will include all calls in the study period. With approximately 125 OHCA calls at the EMDC per month, this gives an expected data collection period for OHCA calls of 12-13 weeks. If data collection produces fewer calls than expected, data collection will continue until 350 calls are collected in total, ending data collection a full week after the aim is reached. Calculations are based on the TTFC data from Copenhagen EMS in two consecutive months in late 2018. A 31% decrease in TTFC is set as the clinically relevant decrease based on the AHA's DA-CPR minimal acceptable performance recommendations of

median amount of time <120 seconds from address acquisition to first DA-CPR directed compression[34].

SIMULATION TRAINING SET-UP

The intervention group begins LDHF dispatcher training with one introduction week followed by 12 weeks of LDHF training. EMDs not working during the introduction week, will start their introduction week when they have their first shift after the study has started. Their LDHF training period will end at the same time as the rest of the EMDs and they will therefore receive fewer training sessions overall. The simulation-based training sessions take place at the EMDC, at extra workstations set-up as ordinary EMD workstations in an out-of-the-way area. Before each session, the EMD is informed about the simulation call and receives instructions concerning technical differences from a regular call (see appendix 1). The instructor acts as a "standardised caller", guided by a computer program. This program, the Danish version of Resuscitation Quality Improvement for Telecommunicators (ROI-T) (Laerdal Medical AS, Stavanger, Norway), is a training program for DA-CPR based on the simulation platform Laerdal Learning Application (LLEAP). This modified version of the RQI-T program has, one test scenario, one data collection scenario and six different cardiac arrests scenarios as well as a feedback checklist based on the Danish dispatcher protocol Danish Index for Emergency Care. The instructor facilitates a standardised scenario with a scripted course of events including scripted lines. Only scenarios where callers are laypersons not trained in basic life support (BLS) will be given during the study. According to Danish Index for Emergency Care the EMDs should then guide in compression only CPR – they will therefore not be trained in ventilations instructions. Some scenarios include an automated external defibrillator (AED). All EMDs will be presented for a short test scenario without feedback for familiarisation and then for the simulation data collection scenario with feedback. In the training phase, EMDs in the intervention group will be presented to the scenarios one through six in numerical order and then start over, going through the same six scenarios again approximately halfway through the study period. The simulation data collection scenario is the same for in the first and last week. Every time the EMD achieves one of the items on the feedback checklist, the scenario will inform the instructor about the next action or line – ensuring standardisation of the scenarios. When the call ends, the instructor provides feedback to the EMD, in-person, using the integrated structured feedback module that presents the results of the feedback checklist. Results from the feedback module will be used to assess the EMD's performance from training session to training session to provide adaptive feedback. Therefore, an adaptive approach to feedback will be used by registering three feedback points in a logbook and presenting these key points from last simulation before each new simulation. Each simulation session takes approximately 20 minutes, including introduction and feedback.

During the study period, all regular quality improvement (QI) activities, such as self-audits, case reviews, mentor groups, and status meetings will continue for all EMDs. Four EMDs (two paramedics and two registered nurses) will, prior to assessment of eligibility of all other EMDs, be asked by the research group to facilitate the simulation-based training. These four EMDs will not be assessed for eligibility to participate in the study.

DATA COLLECTION

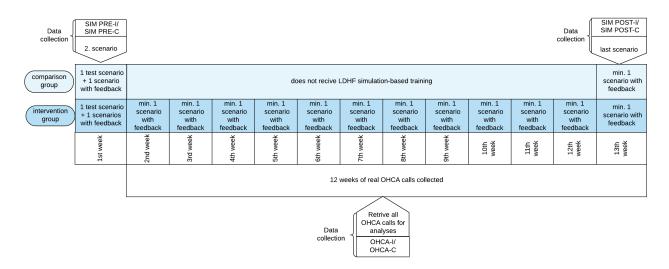
Collection of data from simulated OHCA calls

The introduction week consists of one short test scenario without feedback (for familiarisation), followed by one scenario with structured feedback (scenario "DATA") – the audio recording from the second scenario will form the data: "simulation pre-intervention – intervention group" (SIM PRE-I). During LDHF training, the intervention group will receive one scenario per week in the following 12 weeks. In week 13 (last week), a scenario (scenario "DATA") will be presented to the intervention group forming the data: "simulation post-intervention – intervention group" (SIM POST–I).

The comparison group will also receive the same short test scenario without feedback (for familiarisation) followed by one scenario with structured feedback (scenario "DATA") – the audio recording from the second scenario will form the data: "simulation pre-intervention – comparison group" (SIM PRE-C). In week 13 (last week), a scenario (scenario "DATA") will be presented to the comparison group forming the data: "simulation post-intervention – comparison group" (SIM POST–C). A timeline overview is given in figure 2.

The data set used for the primary analysis is a full analysis set only excluding EMDs if no intervention is applied at all or if no data is available after randomisation.

Figure 2 – timeline



OHCA: Out-of-hospital cardiac arrest; min: minimum; SIM PRE: simulation pre-intervention; SIM POST: simulation post-intervention; I: intervention group; C: comparison group

Collection of data from real OHCA calls

Real OHCA calls handled by the EMDs in the intervention group will only be retrieved for evaluation after the individual EMDs have received their first simulation training session while real OHCA calls handled by the EMDs in the comparison group will be retrieved for evaluation from the first day of the introduction week.

Real OHCA calls from week one through 13 – the introduction week and the 12-week training period – handled by the enrolled EMDs will be retrieved and evaluated according to the outcome measures – these calls will form the data "real OHCA – intervention group" (OHCA-I) and the "real OHCA – comparison group" (OHCA-C).

Only calls handled by EMDs included in the study will be included in the data analysis.

The study group has adopted the definition of a recognised cardiac arrest as well as the data collection strategy recommended in the systematic review by Viereck et al. [29]:

- Recognition is assessed by evaluating emergency call recordings.
- Recognition of OHCA is defined as a call where the caller or the EMD, expresses the
 presence of "OHCA" or the need for "CPR" or an "AED".
- Exclusion criteria for calls are:
 - o EMS-witnessed OHCA.
 - o Missing/corrupted emergency call recording within 120 seconds.

- o Calls where the patient was obviously alive during the call.
- o Calls where bystander CPR was initiated prior to the emergency call.
- Calls where the caller was unable to assess the patient (e.g. caller not being together with the patient).
- Data will be reported using a standardised flowchart (see figure 3).

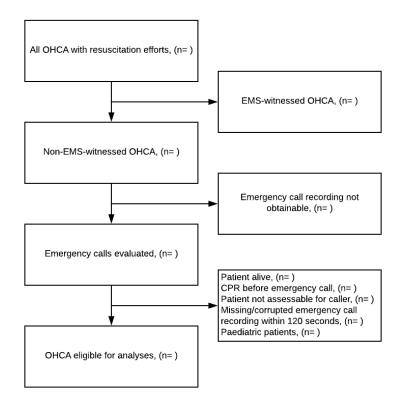
All calls meeting exclusion criteria will be excluded from all analysis.

In addition, all paediatric OHCA calls are excluded as the training alone is for adult cases. Paediatric calls are defined as patient age <18 years.

All OHCA calls are initially identified by including all EMD call recordings marked as OHCA at the Copenhagen EMS and by comparing these to the Danish Cardiac Arrest Registry. The data collection of 1-1-2 emergency calls for OHCA recognition is shown in figure 3.

Numeric data will be presented as medians with interquartile ranges, and categorical data will be presented as numbers with percentage. The following demographic data regarding patient will be collected: age (years), sex (male/female), etiology of cardiac arrest (cardiac or noncardiac), location (public/private), witnessed (yes/no), time to EMS arrival (seconds).

Figure 3 – Flowchart describing the data collection process of 1-1-2 emergency calls for OHCA recognition.



OHCA: Out-of-hospital cardiac arrest; EMS: Emergency medical services; CPR: Cardiopulmonary resuscitation; (n=) will be listed at the end of the study.

DATA COLLECTION AND CLASSIFICATION

Both simulated and real OHCA calls outcomes will be reported by a questionnaire filled in by auditors listening to recordings of all included calls. Auditors evaluating calls are not involved in writing the protocol or manuscript, and the audio recordings will be blinded to group allocation. The questionnaire is a modified version of the Cardiac Arrest Registry to Enhance Survival (CARES) DA-CPR Data Dictionary protocol for OHCA calls, which originally consisted of 22 questions whereby the quality of the call is evaluated[35]. During the review of audio recordings, the 31 assessment points in the modified questionnaire, table 1, will be documented. Instructions for coding in appendix 2, ensure consistency during the review process.

To assess quality of data review, an inter-rater reliability test will be performed on a sample of calls using Cohen's kappa for binary outcomes and intra-class correlation coefficient for continuous outcomes[36]. Auditors allocated to perform the audio reviews will receive two hours of training to practice the documentation process.

Table 1 – Questionnaire content for simulated and real OHCA calls

	Result (time or
Assessment points	yes/no/NA)
Time of EMD addressing caller	(seconds)
Cardiac arrest before arrival of EMS?	(yes/no)
CPR already in progress?	(yes/no)
Consciousness addressed?	(yes/no)
Patient conscious?	(yes/no)
Breathing addressed?	(yes/no)
Patient breathing normally?	(yes/no)
"No - No - Go" approach, used?	(yes/no)
Normal/abnormal breathing addressed?	(yes/no)
Need for CPR recognized?	(yes/no)
Time of recognition	(seconds)
BLS competence addressed?	(yes/no)
CPR instructions started?	(yes/no)
Time of instructions started	(seconds)
Barriers to CPR?	(yes/no)
EMD assertive when giving CPR instructions?	(yes/no)
Speed and depth of compressions addressed?	(yes/no)
Using encouraging and motivating techniques when instructing?	(yes/no)
Chest compressions started?	(yes/no)
Time to first compression	(seconds)
AED addressed?	(yes/no)
AED connected to the patient?	(yes/no)
Did the AED deliver a shock to the patient?	(yes/no)
Cardiac arrest witnessed by another person?	(yes/no)
Call continued until EMS arrival?	(yes/no)
Male sex of caller?	(yes/no)
Caller is alone at the time of call?	(yes/no)
Caller is a relative or friend of the patient?	(yes/no)
Caller has easy access to assess the patient?	(yes/no)

Caller is emotionally distressed? (yes/no)

Other comments?

STATISTICS

The primary outcome analyses investigate the effect of the intervention (LDHF training) on time to first compression in real OHCA calls. This continuous primary outcome will be presented descriptively with median and interquartile. The effect of the intervention will be tested using a Poisson regression of the incidence rate of first compression. First compression is the outcome and the logarithm of time to first compression is the offset value. To account for the hierarchical data structure with OHCA nested within EMDs a random effect of EMDs within intervention is included in the model. The relative effect of the intervention compared to the comparison group on time to first compression is presented as an incidence rate ratio (IRR) and a corresponding 95% confidence interval. The frequency of OHCA calls will vary between EMDs due to the random call distribution.

The binary secondary outcomes in real OHCAs: EMD did not ask irrelevant questions prior to clarifying consciousness/breathing, EMD recognises cardiac arrest, EMD starts DA-CPR instructions, bystander starts CPR and EMD starts DA-CPR instructions on non-cardiac arrest, will be presented descriptively with numbers and percentages. The effect of the intervention will be tested using a logistic regression analysis with a random effect of EMDs within intervention included in the model. The relative effect will be presented as odds ratios (OR) with 95% confidence intervals.

The continuous secondary outcomes related to the simulations: time to first compression, will be presented descriptively with median and interquartile. The binary secondary outcomes related to the simulation: EMD did not ask irrelevant questions prior to clarifying consciousness/breathing, EMD addressed BLS competence, EMD assertive or passive when giving CPR instructions, EMD addressed speed and depth of compressions, EMD using encouraging and motivating techniques when instructing, will be presented descriptively with numbers and percentages. The effect of the intervention will be tested for SIM POST-I versus SIM POST-C adjusted for the baseline (SIM PRE-I + SIM PRE-C) and presented as odds ratio with a 95% confidence interval.

A difference for the primary and secondary outcomes, except the outcome EMD starts DA-CPR instructions on patient without cardiac arrest (yes/no), between simulation data from the two groups

after the training period – SIM POST-I and SIM POST-C – will be tested. Additionally, we will test for a difference in the outcome measures before and after training for each group.

A two-sided alpha level of 5% is considered statistically significant.

Incidence, sensitivity and positive predictive value of OHCA recognition will be presented.

Annette Kjær Ersbøll, National Institute of Public Health, University of Southern Denmark, Copenhagen, Denmark, will be responsible for the statistics – and will refine the existing statistical protocol. The final statistical analysis plan will be completed prior to the start of data collection.

ETHICAL ASPECTS

The study is registered by the Danish Data Protection Agency via The Capital Region of Denmark (J.No.: VD-2018-28, I-Suite No.: 6222). The study has also been registered with the Danish Patient Safety Authority (3-3013-2721/1). The Regional Danish Ethical Committee waived a formal review of the study (J.No.: H-19041425).

Individual Participant Data (IPD) Sharing Statement according to ICMJE Requirements:

Will individual participant data be available (including data dictionaries)?	Yes
What data in particular will be shared?	Individual participant data that underlie the results reported in the article, after deidentification (text, tables, figures, and appendices).
What other documents will be available?	Study Protocol, Statistical and Analysis Plan, Informed Consent Form, Clinical Study Report, Analytic Code.
When will data be available (start and end dates)?	Immediately following publication. Until 31st of December 2021.
With whom?	Anyone who wishes to access the data.
For what types of analyses?	Any purpose.
By what mechanism will data be made available?	Data are available Until 31st of December 2021 at (link to be included after publication).

TIME SCHEDULE

Starting mid-September 2019, data collection and LDHF training will continue for 13-weeks until the start December 2019. Upon enrolment written consent is obtained, and all EMDs will be

randomised at the same time, approximately one week prior to study start. Analysis of data and writing of manuscript is expected to finish in late 2020.

DISSEMINATION OF RESULTS

The results will be submitted to an international peer-reviewed journal and presented at relevant congresses, regardless of findings. The protocol will be made publicly available before data collection begins.

FINANCING

The study is financed by an unrestricted research grant from TrygFonden.

Table 2 - Budget

Budget item	Cost (DKK)
Training of four EMDs as simulation instructors	13,152 DKK
Randomisation	1,176 DKK
Extra staffing at the EMDC during the one-week introduction week	28,770 DKK
Extra staffing at the EMDC during the 12-week training/project period	105,216 DKK
Equipment	8,000 DKK
Data extraction of simulation tests	32,941 DKK
Data extraction from real OHCA calls	22,058 DKK
Scholarship, four months	40,000 DKK
Conference presentation	12,060 DKK
Open access publication	19,697 DKK
Total	283,071 DKK

All hours for simulation-based training of the EMDs in the intervention group are registered as extra costs since the training is in addition to the usual quality improvement activities and therefore not part of the scheduled hours. In addition, the hours are budgeted to avoid that the training, and thus, the data quality is compromised by the lack of capacity for the EMDs to leave their workstations to participate in the study.

RELATIONSHIP BETWEEN TRYGFONDEN AND INVESTIGATORS

Investigators Freddy Lippert, Kristine Elisabeth Eberhard Anne Lippert, Gitte Linderoth, Anders Granholm, Annette Kjær Ersbøll and Fredrik Folke has previously received grants from TrygFonden. The investigators are otherwise independent of TrygFonden.

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- 1. Larsen, M.P., et al., *Predicting survival from out-of-hospital cardiac arrest: a graphic model.* Ann Emerg Med, 1993. **22**(11): p. 1652-8.
- 2. Valenzuela, T.D., et al., *Estimating effectiveness of cardiac arrest interventions: a logistic regression survival model.* Circulation, 1997. **96**(10): p. 3308-13.
- 3. Hasselqvist-Ax, I., et al., *Early cardiopulmonary resuscitation in out-of-hospital cardiac arrest.* N Engl J Med, 2015. **372**(24): p. 2307-15.
- 4. Rea, T.D., et al., *Dispatcher-assisted cardiopulmonary resuscitation and survival in cardiac arrest.* Circulation, 2001. **104**(21): p. 2513-6.
- 5. Takei, Y., et al., Recruitments of trained citizen volunteering for conventional cardiopulmonary resuscitation are necessary to improve the outcome after out-of-hospital cardiac arrests in remote time-distance area: A nationwide population-based study. Resuscitation, 2016. **105**: p. 100-8.
- 6. Culley, L.L., et al., *Dispatcher-assisted telephone CPR: common delays and time standards for delivery.* Ann Emerg Med, 1991. **20**(4): p. 362-6.
- 7. Bobrow, B.J., et al., *Implementation of a Regional Telephone Cardiopulmonary Resuscitation Program and Outcomes After Out-of-Hospital Cardiac Arrest.* JAMA Cardiol, 2016. **1**(3): p. 294-302.
- 8. Teo, M.H.N., et al., *The use of dispatcher assistance in improving the quality of cardiopulmonary resuscitation: A randomised controlled trial.* Resuscitation, 2019. **138**: p. 153-159.
- 9. Park, J.H., et al., Dispatcher-assisted bystander cardiopulmonary resuscitation in rural and urban areas and survival outcomes after out-of-hospital cardiac arrest. Resuscitation, 2018. 125: p. 1-7.
- 10. Hiltunen, P.V., et al., *Emergency dispatch process and patient outcome in bystander-witnessed out-of-hospital cardiac arrest with a shockable rhythm.* Eur J Emerg Med, 2015. **22**(4): p. 266-72.
- 11. Wu, Z., et al., *Telephone cardiopulmonary resuscitation is independently associated with improved survival and improved functional outcome after out-of-hospital cardiac arrest.* Resuscitation, 2018. **122**: p. 135-140.
- 12. *Ten Programs*. 2017 [cited 2019 September 02]; Available from: https://www.globalresuscitationalliance.org/ten-programs/#1505402690639-0a57bed7-9bc2.
- 13. Eisenberg, M., Resuscitation Academy. 10 Steps for Improving Survival from Sudden Cardiac Arrest. 2013.
- 14. Neumar, R.W., et al., *Part 1: Executive Summary: 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care.* Circulation, 2015. **132**(18 Suppl 2): p. S315-67.
- 15. Perkins, G.D., et al., European Resuscitation Council Guidelines for Resuscitation 2015: Section 2. Adult basic life support and automated external defibrillation. Resuscitation, 2015. **95**: p. 81-99.
- 16. Eisenberg, M., et al., Improving Survival from Out-of-Hospital Cardiac Arrest
- Acting on the Call. 2018, The Global Resuscitation Alliance.
- 17. Akahane, M., et al., *Impact of telephone dispatcher assistance on the outcomes of pediatric out-of-hospital cardiac arrest.* Crit Care Med, 2012. **40**(5): p. 1410-6.
- 18. Tanaka, Y., et al., *The continuous quality improvement project for telephone-assisted instruction of cardiopulmonary resuscitation increased the incidence of bystander CPR and improved the outcomes of out-of-hospital cardiac arrests.* Resuscitation, 2012. **83**(10): p. 1235-41.

- 19. *Dansk Indeks for Akuthjælp* 2017 [cited 2019 September 02]; Available from: http://www.ph.rm.dk/siteassets/prahospitalet/prahospitale-omrader/amk-vagtcentral/dansk-indeks-1.8---landsudgaven.pdf.
- 20. Andersen, M.S., et al., *Implementing a nationwide criteria-based emergency medical dispatch system: a register-based follow-up study.* Scand J Trauma Resusc Emerg Med, 2013. **21**: p. 53.
- 21. *Norsk indeks for medisinsk nødhjelp 3. utgave*. 2009 [cited 2019 September 02]; Available from: https://docplayer.me/261978-I-n-d-e-k-s-n-o-r-s-k-norsk-indeks-for-medisinsk-nodhjelp-3-utgave-informasjon-om-bestilling-av-denne-boken.html.
- 22. The Road to Recognition and Resuscitation The Role of Telecommunicators and Telephone-CPR QI in Cardiac Arrest Survival. 2017 [cited 2019 September 01]; Available from: http://www.resuscitationacademy.org/downloads/DACPRToolkit1010.pdf.
- 23. Meischke, H., et al., Simulation training to improve 9-1-1 dispatcher identification of cardiac arrest: A randomized controlled trial. Resuscitation, 2017. 119: p. 21-26.
- 24. Andersen, M.S., et al., *Preventable deaths following emergency medical dispatch--an audit study.* Scand J Trauma Resusc Emerg Med, 2014. **22**: p. 74.
- 25. Ellensen, E.N., et al., *Dispatch guideline adherence and response interval-a study of emergency medical calls in Norway.* BMC Emerg Med, 2016. **16**(1): p. 40.
- 26. Painter, I., et al., Changes to DA-CPR instructions: can we reduce time to first compression and improve quality of bystander CPR? Resuscitation, 2014. **85**(9): p. 1169-73.
- 27. Ong, M.E.H., et al., *Improvements in bystander CPR rates and survival for Out-of-Hospital Cardiac Arrest with a comprehensive dispatcher-assisted CPR program in Singapore*. Resuscitation, 2018. **130**: p. e25.
- 28. Ng, Y.Y., S.H. Leong, and M.E. Ong, *The role of dispatch in resuscitation*. Singapore Med J, 2017. **58**(7): p. 449-452.
- 29. Viereck, S., et al., *Recognition of out-of-hospital cardiac arrest during emergency calls a systematic review of observational studies.* Scand J Trauma Resusc Emerg Med, 2017. **25**(1): p. 9.
- 30. Schulz, K.F., et al., *CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials.* BMJ, 2010. **340**: p. c332.
- 31. Chan, A.W., et al., *SPIRIT 2013 statement: defining standard protocol items for clinical trials.* Ann Intern Med, 2013. **158**(3): p. 200-7.
- 32. Denmark, S. *StatBank Denmark*. 2019 [cited 2019 September 02]; Available from: https://www.statbank.dk/statbank5a/default.asp?w=1440.
- 33. Donner, A. and N. Klar, *Statistical considerations in the design and analysis of community intervention trials.* J Clin Epidemiol, 1996. **49**(4): p. 435-9.
- 34. Association, A.H. *Telephone CPR (T-CPR) Program Recommendations and Performance Measures*. 2019 [cited 2019 September 02]; Available from: https://cpr.heart.org/AHAECC/CPRAndECC/ResuscitationScience/UCM_477526_CPR-Emergency-Medical-Dispatcher-CPR-Instructions.jsp.
- 35. CARES. *CARES Dispatcher-Assisted CPR Data Dictionary 12-6-15*. 2015 [cited 2019 September 02]; Available from: https://mycares.net/sitepages/uploads/2015/CARES%20Dispatcher-Assisted%20CPR%20Data%20Dictionary%2012-6-15.pdf.
- 36. Ranganathan, P., C.S. Pramesh, and R. Aggarwal, *Common pitfalls in statistical analysis: Measures of agreement.* Perspect Clin Res, 2017. **8**(4): p. 187-191.

Protocol version 2